Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HOWARD L. ELFORD

Appeal No. 2002-0455
Application No. 09/123,620

ON BRIEF

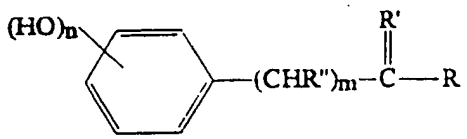
Before WINTERS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 2-11 and 14, all of the claims remaining. Claim 14 is representative and reads as follows:

14. A process for inhibiting NF-κB in a mammalian cell in which NF-κB has been activated by an agency external to said cell which comprises administering to the mammal in whose cells NF-κB has been activated an NF-κB inhibiting amount of a drug represented by the formula:



wherein n is 2-5, m is 0 or 1, R is NH_2, NHOH, OC_{1-3}alkyl, or O-phenyl, R' is O, NH or NOH, R" is H or OH, or a pharmaceutically-acceptable acid addition salt or acylated phenol derivative thereof.

The examiner relies on the following reference:

van't Riet et al. (van't Riet) 4,623,659 Nov. 18, 1986

Claims 2-11 and 14 stand rejected under 35 U.S.C. § 103 as obvious in view of van't Riet and "appellant's admission."

We reverse.

Background

The specification discloses that nuclear factor kappa B (NF-κB) is a transcription factor that "appears to play an important role in the etiology and progress of inflammatory disease, both chronic and acute." Page 1. "NF-κB is rapidly activated by a wide variety of stimuli including cytokines, protein kinase C activators, viruses, ultraviolet radiation, immune stimuli and agents inducing oxidative stress." Id. "Antioxidants have been shown to inhibit the oxidative stress activation of NF-κB." Id., page 2. The specification also discloses that "the inhibition of NF-κB may enhance the anticancer activity of a number of chemotherapeutic agents that cause cell damage leading to cell suicide via the apoptotic process." Page 4.

The specification discloses that certain free-radical scavenging compounds, which were known in the art, inhibit NF-κB activity. See, e.g., page 6. Thus, for example, the compounds "may be administered in saline to

mammals in whom NF-κB has been triggered by inflammation, a viral disease, radiation or an anticancer drug." Id., pages 6-7.

Discussion

The claims are directed to a method of inhibiting NF-κB in a mammalian cell, in which NF-κB has been activated, by administering to the mammal an NF-κB-inhibiting amount of a drug corresponding to a particular formula.

The examiner rejected the claims as obvious in view of a prior art patent (van't Riet) disclosing the same compounds recited in the instant claims, and also disclosing that the compounds are inhibitors of ribonucleotide reductase and free radical scavengers. See the Examiner's Answer, page 3. The examiner also relied on Appellant's "admission" in the specification that antioxidants were known to inhibit activation of NF-κB. See id., page 4. She concluded that

> [i]t would have been obvious for a person of ordinary skill in the art at the time of the invention to inhibit NF-κB in a mammalian cell by administration of a hydroxybenzoic acid or derivative thereof. Because the compounds are taught by VAN'T RIET et al. to be ribonucleotide [reductase] inhibitors and free radical scavengers, an ordinarily skilled chemist would immediately recognize them to be anti-oxidants. Appellant had admitted that it was known in the art at the time of the invention that anti-oxidants inhibit activation of NF-κB. Therefore, an ordinarily skilled worker would have been motivated, with a reasonable expectation of success, to inhibit NF-κB in a mammalian cell by administration of a hydroxybenzoic acid or derivative thereof.

Id.

Appellant takes issue with the examiner's position that a skilled artisan would recognize free radical scavengers and ribonucleotide reductase inhibitors as antioxidants. See, e.g., the Appeal Brief at page 4: "[T]o use the term 'anti-

oxidant when referring to free-radic[a]l chain reactions and one-electron transfers is to torture the accepted meaning of 'anti-oxidant' beyond recognition. Anti-oxidants prevent the reaction of oxygen, peroxides etc[.] with substrates. These reactions all involve two-electron transfers which permanently, and not transitorially, change the oxidation state of the compound being oxidized."

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). "Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

In this case, the examiner has not carried her initial burden of showing prima facie obviousness. We cannot agree with the examiner's rationale that the specification admits that antioxidants were known to inhibit NF-κB, and that a person of ordinary skill in the art would recognize that van't Riet's compounds were antioxidants because of their free radical scavenging and ribonucleotide reductase inhibiting activities.

First of all, the examiner has cited no evidence to support her position that those of skill in the art would have recognized that antioxidant activity would be

inherent in a compound with free radical scavenging and/or ribonucleotide reductase inhibiting activity. Appellant has argued that "oxidation-reduction reactions and free-radical chain reactions involve comple[te]ly disparate chemistry and are never suggestive of one another." Appeal Brief, page 2.

In response, the examiner has presented reasoning to support her position. See the Examiner's Answer, page 5. However, the examiner has presented no evidence to show that those of skill in the art would have recognized van't Riet's compounds, which were disclosed as free radical scavengers and ribonucleotide reductase inhibitors, as antioxidants that would be suitable for and likely to be effective as inhibitors of NF-κB.

While Appellant has not cited any evidence to support his reading of the prior art, neither has the examiner. A lack of evidence on either side, however, favors the applicant, since the examiner bears the burden of proving unpatentability. As Judge Posner recently put it in a similar context, "in a finger-pointing contest [the patentee] must lose because it bears the burden of proving infringement." SmithKline Beecham Corp. v. Apotex Corp., No. 98 C 3952, 2003 U.S. Dist. LEXIS at *73 (N.D. Ill. 2003).

In addition, while the specification does state that "[a]ntioxidants have been shown to inhibit the oxidative stress activation of NF-κB," page 2, it does not state that all antioxidants would be expected to be NF-κB inhibitors. Nor has the examiner provided any evidence independently to show that any compound that could be construed as an antioxidant would be expected to be an inhibitor of NF-κB. Thus, even assuming arguendo that those skilled in the art would have

recognized van't Riet's compounds as, in some sense, antioxidants, the examiner has not shown that a skilled artisan would have reasonably expected them to effectively inhibit NF-κB if administered in accordance with the instantly claimed process.

Other Issues

Appellant has recently been issued U.S. Patent 6,248,782. Claim 2 of that patent appears to be directed to a method of treating retroviral infection by administering to a mammal the same compounds as are recited in the instant claims. The instant specification discloses that NF-κB can be activated by, inter alia, virus infection. See pages 1 and 6-7. See also page 2: "[I]nhibition of NF-κB could also play a role in the treatment of HIV-1 and other viral agents."

Upon return of this case, the examiner should consider whether the treatment of virus infection that is claimed in the '782 patent is merely a species of the instantly claimed treatment of NF-κB activation. If so, a rejection for obviousness-type double patenting may be appropriate. See Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 632, 2 USPQ2d 1051, 1054 (Fed. Cir. 1987) (Discovery of a property inherent to a prior art process does not render that process patentable, even if the prior art did not appreciate the property.); Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 970, 58 USPQ2d 1869, 1879-80 (Fed. Cir. 2001) (holding that a method of blocking serotonin uptake by administering a compound was not patentably distinct from a method of treating anxiety by administering the same compound).

In addition, the examiner should consider whether instant claims 9-11 have adequate descriptive support in the specification. In reviewing the specification, we were unable to find express support for the limitations of these claims, and we note that when the claims were first submitted, Appellant did not point to support for them in any specific part of the specification. Literal support, of course, is not required, see Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000), but the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. See id. The examiner should consider whether this requirement has been met with respect to claims 9-11.

Summary

The examiner has not carried the burden of showing, by a preponderance of the evidence, that the claimed method would have been obvious to a person of skill in the art. We therefore reverse the rejection under 35 U.S.C. § 103.

REVERSED

Sherman D. Winters)
Administrative Patent Judge)
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